FIBRILLATION/TACHYCARDIA MONITORING AND PREVENTIVE SYSTEM AND METHODOLOGY

FIELD OF THE PRESENT INVENTION

The present invention relates generally to an implantable device that is capable of monitoring cardiac conditions and preventing tachycardia. More particularly, the present invention is directed to an implantable system that monitors cardiac electrical signals to determine a convergence upon uniformity and applies electrical noise into the cardiac environment to break-up the convergence upon uniformity.

CROSS REFERENCE TO RELATED PATENT APPLICATIONS

The subject matter of co-pending US Patent Application Serial Number 09/885,867, filed on June 20, 2001, entitled "Controllable, Wearable MRI-Compatible Cardiac Pacemaker With Pulse Carrying Photonic Catheter And VOO Functionality"; co-pending US Patent Application Serial Number 09/885,868, filed on June 20, 2001, entitled "Controllable, Wearable MRI-Compatible Cardiac Pacemaker With Power Carrying Photonic Catheter And VOO Functionality"; co-pending US Patent Application Serial Number 10/037,513, filed on January 4, 2002, entitled "Optical Pulse Generator For Battery Powered Photonic Pacemakers And Other Light Driven Medical Stimulation

Equipment"; co-pending US Patent Application Serial Number 10/037,720, filed on January 4, 2002, entitled "Opto-Electric Coupling Device For Photonic Pacemakers And Other Opto-Electric Medical Stimulation Equipment"; co-pending US Patent Application Serial Number 09/943,216, filed on August 30, 2001, entitled "Pulse Width Cardiac Pacing Apparatus"; co-pending US Patent Application Serial Number 09/964,095, filed on September 26, 2001, entitled "Process for Converting Light"; co-pending US Patent Application Serial Number 09/921,066, filed on August 2, 2001, entitled "MRI-Resistant Implantable Device"; co-pending US Patent Application Serial Number 10/077,842, filed on February 19, 2002, entitled "An Electromagnetic Interference Immune Tissue Invasive System"; co-pending US Patent Application Serial Number 10/077,823, filed on February 19, 2002, entitled "An Electromagnetic Interference Immune Tissue Invasive System"; co-pending US Patent Application Serial Number 10/077,887, filed on February 19, 2002, entitled "An Electromagnetic Interference Immune Tissue Invasive System"; co-pending US Patent Application Serial Number 10/077,883, filed on February 19, 2002, entitled "An Electromagnetic Interference Immune Tissue Invasive System"; and co-pending US Patent Application Serial Number 10/077,958, filed on February 19, 2002, entitled "An Electromagnetic Interference Immune Tissue Invasive System".

The entire content of each of the above noted co-pending US Patent Applications (Serial Numbers: 09/885,867; 09/885,868; 10/037,513; 10/037,720; 09/943,216; 09/964,095; 09/921,066; 10/077,842; 10/077,823; 10/077,887; 10/077,883; and 10/077,958) is hereby incorporated by reference.

BACKGROUND OF THE PRESENT INVENTION

The heart is a series of pumps that are carefully controlled by a very special electrical system. This electrical system attempts to regulate the heart rate between 60 and 100 beats per minute. With normal conduction, the cardiac contractions are very organized and timed so that the top chambers (the atria) contract before the lower chambers and the heart rate is maintained between 60 and 100 beats per minute.

Abnormally fast heart rates, called tachycardias, occur when the ventricular chambers beat too quickly. In such an instance, the ventricles may not be able to fill with enough blood to supply the body with the oxygen rich blood that it needs.

Conventionally, ventricular tachycardia ("VT") has been controlled by medication and electrical methods. The most common conventional electrical therapy for VT is implantation of a device known as an Implantable Cardioverter Defibrillator or ICD.

The conventional ICD applies an electric shock to the heart muscle to interrupt or disrupt the fast rhythm. The electric shock may be in the form of specially timed pacemaker pulses (unfelt by the patient), called antitachycardia pacing, and/or by high voltage shock. The high voltage shock, if required, is usually felt by the patient.

Cardiac pacers, which provide stimulation to a patient's heart, by means of amplitude and frequency modulated electrical pulses, have been developed for permanent or temporary applications. The two most common types of cardiac pacers currently in use are pacemakers and implantable cardioverter-defibrillators (ICD). Cardiac pacers can be implanted in a suitable location inside the patient's body or located outside the patient's body.

The human heart may suffer from two classes of rhythmic disorders or arrhythmias: bradycardia and tachyarrhythmia. Bradycardia occurs when the heart beats too slowly, and may be treated by a common implantable pacemaker delivering low voltage (about 3 V) pacing pulses.

The conventional implantable pacemaker is usually contained within a hermetically sealed enclosure, in order to protect the operational components of the device from the harsh environment of the body, as well as to protect the body from the device. This implantable pacemaker operates in conjunction with one or more electrically conductive leads, adapted to conduct electrical stimulating pulses to sites within the patient's heart, and to communicate sensed signals from those sites back to the implanted device.

Furthermore, the conventional implantable pacemaker typically has a metal case and a connector block mounted to the metal case that includes receptacles for leads which may be used for electrical stimulation or which may be used for sensing of physiological signals. The battery and the circuitry associated with the common implantable pacemaker are hermetically sealed within the case. Electrical interfaces are employed to connect the leads outside the metal case with the medical device circuitry and the battery inside the metal case.

Electrical interfaces serve the purpose of providing an electrical circuit path extending from the interior of a hermetically sealed metal case to an external point outside the case while maintaining the hermetic seal of the case. A conductive path is provided through the interface by a conductive pin that is electrically insulated from the case itself.

Such interfaces typically include a ferrule that permits attachment of the interface to the case, the conductive pin, and a hermetic glass or ceramic seal that supports the pin within the ferrule and isolates the pin from the metal case.

In all of the conventional electrical stimulus devices, the conventional ICD senses a fibrillation or tachycardia cardiac state and proceeds to use various measures to bring the heart out of the fibrillation or tachycardia, through defibrillation by antitachycardia pacing, and/or by high voltage shock. In other words, the heart has already reached a dangerous state before the conventional ICDs provide any stimulus to rectify the problem.

Therefore, it is desirable to have a device that can sense or detect an approaching fibrillation or tachycardia cardiac state and take remedial actions prior to the heart entering a dangerous state. Moreover, it is desirable to have a device that can sense or detect a failure of remedial actions and provide, as a backup remedy, the conventional defibrillation by antitachycardia pacing, and/or by high voltage shock.

SUMMARY OF THE PRESENT INVENTION

A first aspect of the present invention is a cardiac assist device. The cardiac assist device includes a primary device housing; a sensor to sense conditions of a heart; and a lead system to transmit and receive signals between the heart and the primary housing. The primary device housing includes a control circuit, in operative communication with the sensor, to control generation of various electrical stimuli in response to sense conditions of the heart; a chaos control generator to generate an electrical signal so as to bring a pre-fibrillated heart condition back into a normal beating condition when the control circuit determines from the sensed conditions a pre-state of fibrillation; and a pacing environment enhancement generator to generating an electrical enhancement signal that causes a threshold of pacing cells in the heart to be exceeded in response to a

subthreshold stimulus when control circuit determines from the sensed conditions a subthreshold pacing signal.

A second aspect of the present invention is a method for assisting a heart beat normally. The method senses conditions of a heart; determines a state of the heart from the sensed conditions; generates a control electrical signal so as to bring a pre-fibrillated heart condition back into a normal beating condition when the determined state of the heart is a pre-state of fibrillation, and generates an electrical enhancement signal that causes a threshold of pacing cells in the heart to be exceeded in response to a subthreshold stimulus when the determined state of the heart is a state associated with a subthreshold pacing signal.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention may take form in various components and arrangements of components, and in various steps and arrangements of steps. The drawings are only for purposes of illustrating a preferred embodiment and are not to be construed as limiting the present invention, wherein:

Figure 1 illustrates one embodiment of a cardiac assist system according to the concepts of the present invention;

Figure 2 illustrates an example of a Poincaré map used by the present invention to manage the generation of electrical stimulus during a pre-fibrillation stage;

Figures 3 and 4 illustrate further embodiments of a cardiac assist system according to the concepts of the present invention; and

Figure 5 is a flowchart illustrating the management of a heart according to the concepts of the present invention.

DETAILED DESCRIPTION OF THE PRESENT INVENTION

The present invention will be described in connection with preferred embodiments; however, it will be understood that there is no intent to limit the present invention to the embodiments described herein. On the contrary, the intent is to cover all alternatives, modifications, and equivalents as may be included within the spirit and scope of the present invention as defined by the appended claims.

For a general understanding of the present invention, reference is made to the drawings. In the drawings, like reference have been used throughout to designate identical or equivalent elements. It is also noted that the various drawings illustrating the present invention are not drawn to scale and that certain regions have been purposely drawn disproportionately so that the features and concepts of the present invention could be properly illustrated.

Current medical research has demonstrated that fibrillation has three detectable stages wherein some intervention is needed by the second stage to prevent fibrillation or actual intervention at the third stage to cause defibrillation. Moreover, from this research, it appears that fibrillation is not necessarily an immediate situation, but fibrillation is a breaking down, over a period of time, of a stable cardiac system into a chaotic cardiac system to finally a pseudo-random cardiac system and heart failure.

Of the stages discussed above, the first stage is a warning stage wherein warning signs are produced indicating that the heart beating may be progressing towards the realization of fibrillation; the second stage is the onset of fibrillation, thus intervention is critical to avoid heart failure and the need for a defibrillation stimulus to bring the heart back into proper rhythm. It is these first two stages that the present invention provides a non-defibrillation stimulus to bring the heart back into proper rhythm. Moreover, the present invention proposes a pre-warning stage wherein a sub-threshold stimulus is provided as a preventive means to avoid the heart from entering the first warning stage of fibrillation.

As illustrated in Figure 1, a medical device **12** is provided to monitor the conditions of the heart and to provide proper stimulus as dictated by the monitored conditions. Although this embodiment of Figure 1 illustrates the medical device **12** as implantable, the medical device **12** may be implantable or non-implantable.

Stimulus leads **14** and **15** are connected to the medical device **12** in connector block region **13** using an interface. It is noted that stimulus leads **14** and **15** may be a fiber optic based communication system wherein the fiber optic communication system contains at least one channel within a multi-fiber optic bundle. The fiber optic based communication system is covered with a biocompatible material wherein the biocompatible material is a non-permeable diffusion resistant biocompatible material.

The stimulus leads **14** and **15** may also be a plurality of electrical leads that have a shield therearound to prevent the electrical leads from conducting stray electromagnetic interference. This shield may be a metallic sheath, a carbon composite sheath, or a polymer composite sheath to prevent the electrical leads from conducting stray electromagnetic interference. In addition to the shield or in lieu of the shield, each electrical lead may include an electrical filter wherein the electrical filter removes stray electromagnetic interference from a signal being received from the electrical lead. The electrical filter may comprise capacitive and inductive filter elements adapted to filter out predetermined frequencies of electromagnetic interference. The shield is covered with a biocompatible material wherein the biocompatible material is a non-permeable diffusion resistant biocompatible material.

The stimulus leads **14** and **15** may be unipolar leads, bipolar leads, or a combination of unipolar and bipolar leads. The stimulus leads **14** and **15** may also be a combination of a fiber optic based communication system and electrical leads. Moreover, the stimulus leads **14** and **15** may be defibrillator leads.

The stimulus leads **14** and **15** may also include a detection circuit (not shown) to detect a phase timing of an external electromagnetic field such that a control circuit alters its operations to avoid interfering with the detected external electromagnetic field.

As further illustrated in Figure 1, a cardiac sensor lead **18** with associated sensor **20** is connected to the implantable medical device **12** in connector block region **13** using an interface. As discussed above, the present invention provides a means for sensing the cardiac conditions and also provides a means for generating stimuli in response thereto.

With respect to monitoring the cardiac conditions, one embodiment of the present invention contemplates that the sensor **20** is a two-dimensional high-definition (high resolution) touch sensitive patch attached to the heart that provides fast frames of pressure readings from individual pressure sites for the two-dimensional area of interest. In this embodiment, the sensor **20** provides pressure readings from the sensed pressure pulses. These pressure readings are correlated to the pulsing of the heart muscle by a microprocessor located within the implantable medical device **12**.

In another embodiment of the present invention, the sensor **20** is a two-dimensional high-definition (high resolution) patch that can measure, capacitively, the

voltage. The voltage sensitive sites would be, for example, individual non-destructive floating-gate charge-sensing amplifiers located in very defined areas without affecting the voltage in other areas.

According to the concepts of the present invention, the information received from the sensor **20** is processed by the microprocessor so as to generate information that is equivalent to a Poincaré map of the sensed situation. Upon this information being internally mapped by the microprocessor, the sequence of the data points is used to determine the stable and unstable directions of the Poincaré map. An example of this determination is illustrated by Figure 2 wherein the determined stable **120** and unstable **110** directions (manifolds) and the unity line **130** of the Poincaré map **100** are shown.

A normal functioning heart will have its points lying along or in very close proximity to the stable manifold **120**. As shown in Figure 2, point **B** represent a condition wherein the system is beginning to become unstable and in the case of the present invention, the heart is showing warning signs of fibrillation. Therefore, when a condition represented by point **B** of Figure 2 is sensed by the present invention, a signal is generated to bring the point from **B** to **B'**. In other words, the signal generated by the present invention provides chaos control by bringing the condition (**B**), as illustrated by a Poincaré map, to a new condition (**B'**) that lies along or is in very close proximity to the stable manifold **120** of the Poincaré map.

In other words, the present invention provides a stimulus to prevent fibrillation. According to the concepts of the present invention the stimulus can be managed in amplitude, frequency, and timing (modulation) to be effective. Moreover, the stimulus may be either positive (in that it enhances the natural signal being generated by the heart) or negative (in that is blocks, dampens, or diminishes the natural signal being generated by the heart). The stimulus brings the sensed conditions back to a normal state (points on the Poincaré map back to unity). Simply put the control unit of the present invention translates the measured conditions into Poincaré space, find the difference between a stable condition in Poincaré space and the measured condition in Poincaré space, and translate the Poincaré space difference to a voltage, current, power, or drug stimulus space so that effective treatment can be realized.

Thus, instead of powerful electric jolts from defibrillator paddles to restore a normal heartbeat, the present invention provides a more gentle stimulation during an early warning stage of fibrillation so as to prevent the full onslaught of fibrillation so as to avoid unnecessary harm or discomfort to the patient.

Figure 3 illustrates another embodiment of the present invention. As illustrated in Figure 3, a primary housing **400** includes a control unit **410** that manages the overall operations of the cardiac assist system or device. The control unit **410** is operatively connected to a memory unit **420** that stores the applications needed to control the cardiac assist device as well as the data associated with the sensed conditions of the heart.

For illustrative purposes, the cardiac assist device of Figure 3 includes a fiber optic communication system comprising an optical bundle 300 having optical fibers **310** and **320**; lasers **440** and **210** to provide optical pulses between the primary housing **400** and a secondary housing **200**; photodiodes **450** and **260** to convert the optical pulses to electrical data signals; and drivers **210** and **340** to convert electrical signals into control signals that cause the optical pulses to be generated.

It is noted that the fiber optic communication system can be replaced with an electrical system, an acoustic system, or a radio transmission system. In such cases the various components described above would be replaced with their equivalent corresponding components.

It is further noted that the fiber optic communication system contains at least one channel within a multi-fiber optic bundle. The fiber optic based communication system is covered with a biocompatible material wherein the biocompatible material is a non-permeable diffusion resistant biocompatible material.

The communication system may also be a plurality of electrical leads that have a shield therearound to prevent the electrical leads from conducting stray electromagnetic interference. This shield may be a metallic sheath, a carbon composite sheath, or a polymer composite sheath to prevent the electrical leads from conducting stray electromagnetic interference. In addition to the shield or in lieu of the shield, each electrical lead may include an electrical filter wherein the electrical filter removes stray electromagnetic interference from a signal being received from the electrical lead. The electrical filter may comprise capacitive and inductive filter elements adapted to filter out

predetermined frequencies of electromagnetic interference. The shield is covered with a biocompatible material wherein the biocompatible material is a non-permeable diffusion resistant biocompatible material.

The communication system may be unipolar leads, bipolar leads, or a combination of unipolar and bipolar leads. The communication system may also be a combination of a fiber optic based communication system and electrical leads.

The communication system may also include a detection circuit (not shown) to detect a phase timing of an external electromagnetic field such that a control circuit alters its operations to avoid interfering with the detected external electromagnetic field.

Figure 3 further illustrates a secondary housing **200** that includes a control unit **270**. The control unit **270** is in operative communication with control unit **410** of the primary housing. It is noted that the cardiac assist device of the present invention may be constructed in a single housing and thus only a single control unit would be needed, as will be described below in more detail with respect to Figure 4.

The secondary housing **200** further includes a sensor **230** to sense the conditions of the heart. The sensor **230** may be integral to the secondary housing **200** or operatively connected to the secondary housing through optical or electrical leads, or a combination thereof.

With respect to monitoring the cardiac conditions, one embodiment of the present invention contemplates that the sensor **230** is a two-dimensional high-definition (high resolution) touch sensitive patch attached to the heart that provides fast frames of pressure readings from individual pressure sites for the two-dimensional area of interest. In this embodiment, the sensor **230** provides pressure readings from the sensed pressure pulses. These pressure readings are correlated to the pulsing of the heart muscle by the control unit **410**.

In another embodiment of the present invention, the sensor **230** is a two-dimensional high-definition (high resolution) patch that can measure, capacitively, the voltage. The voltage sensitive sites would be, for example, individual non-destructive floating-gate charge-sensing amplifiers located in very defined areas without affecting the voltage in other areas.

In a preferred embodiment of the present invention, the information received from the sensor **230** is processed by the control unit **410** so as to generate information that is equivalent to a Poincaré map of the sensed situation. Upon this information being internally mapped by the control unit **410**, the sequence of the data points is used to determine the stable and unstable directions of the Poincaré map. The mapped information is stored in memory **420** for use by the control unit **410**. It is noted that various memory management schemes, such as compression techniques, may be used to effectively store the required amount of data necessary for proper analysis by the control unit **410**. It is preferred that the mapped information be analyzed in its compressed state to conserve memory space.

If a two-dimensional sensor is utilized, the secondary housing **200** would include a frame memory **240** and a register **250** to convert the two-dimensional array of data into a serial data to be transmitted to the primary housing **400**.

The control unit **270** controls the operations of a subthreshold stimulus generator **287**, a chaos management generator **280**, and a defibrillation pulse generator **285**. These various generators are connected to an electrode **290** that is connected to the heart.

When the control unit **410** determines that the natural pacing signal of the heart falls below a threshold to trigger the heart to beat, the control unit **410** generates a signal to control unit **270** instructing the control unit **270** to activate the subthreshold stimulus generator **287**. Subthreshold stimulus generator **287** generates a signal that causes a threshold of pacing cells in the heart to be exceeded in response to a subthreshold pacing signal or natural stimulus.

The signal generated by the subthreshold stimulus generator **287** may be a noise signal; a periodic signal; a high frequency deterministic signal; a randomly fluctuating intensity signal; a randomly fluctuating frequency signal; or any combination thereof. The signal generated by the subthreshold stimulus generator **287** may also be modulated in response to the sensed subthreshold pacing signal.

When the control unit **410** determines that the state of the heart is entering in a pre-fibrillation stage, the control unit **410** generates a signal to control unit **270** instructing the control unit **270** to activate the chaos management generator **280**. Chaos management generator **280** generates a signal that prevents the onslaught of fibrillation.

The stimulus can be managed in amplitude, frequency, and timing (modulation) to be effective. Moreover, the stimulus may be either positive (in that it enhances the natural signal being generated by the heart) or negative (in that is blocks, dampens, or diminishes the natural signal being generated by the heart). The stimulus brings the sensed conditions back to a normal state (points on the Poincaré map back to unity).

Lastly, when the control unit **410** determines that the state of the heart is in a fibrillation stage, the control unit **410** generates a signal to control unit **270** instructing the control unit **270** to activate the defibrillation pulse generator **285**. Defibrillation pulse generator **285** generates a high voltage pulse to defibrillate the heart.

Figure 4 illustrates another embodiment of the present invention that includes a housing **500** and a control unit **570** therein. The housing **500** is operatively connected to a sensor **530** to sense the conditions of the heart. The sensor **530** may be integral to the housing **500** or operatively connected to the housing through optical or electrical leads, or a combination thereof.

With respect to monitoring the cardiac conditions, one embodiment of the present invention contemplates that the sensor **530** is a two-dimensional high-definition (high resolution) touch sensitive patch attached to the heart that provides fast frames of pressure readings from individual pressure sites for the two-dimensional area of interest. In this embodiment, the sensor **530** provides pressure readings from the sensed pressure pulses. These pressure readings are correlated to the pulsing of the heart muscle by the control unit **570**.

In another embodiment of the present invention, the sensor **530** is a two-dimensional high-definition (high resolution) patch that can measure, capacitively, the voltage. The voltage sensitive sites would be, for example, individual non-destructive floating-gate charge-sensing amplifiers located in very defined areas without affecting the voltage in other areas.

In a preferred embodiment of the present invention, the information received from the sensor **530** is processed by the control unit **570** so as to generate information that is equivalent to a Poincaré map of the sensed situation. Upon this information being internally mapped by the control unit **570**, the sequence of the data points is used to determine the stable and unstable directions of the Poincaré map. The mapped

information is stored in second memory **545** for use by the control unit **570**. It is noted that various memory management schemes, such as compression techniques, may be used to effectively store the required amount of data necessary for proper analysis by the control unit **570**. It is preferred that the mapped information be analyzed in its compressed state to conserve memory space.

If a two-dimensional sensor were utilized, the housing **500** would include a memory **540** to convert the two-dimensional array of data into a serial data to be transmitted to the control unit **570**.

The control unit **570** controls the operations of a subthreshold stimulus generator **520**, a pre-fibrillation control generator **550**, and a defibrillation pulse generator **560**. These various generators are connected, via pulse bus **580**, to an electrode **590** that is connected to the heart.

When the control unit **570** determines that the natural pacing signal of the heart falls below a threshold to trigger the heart to beat, the control unit **570** generates a signal to activate the subthreshold stimulus generator **520**. Subthreshold stimulus generator **520** generates a signal that causes a threshold of pacing cells in the heart to be exceeded in response to a subthreshold pacing signal or natural stimulus.

The signal generated by the subthreshold stimulus generator **520** may be a noise signal; a periodic signal; a high frequency deterministic signal; a randomly fluctuating intensity signal; a randomly fluctuating frequency signal; or any combination thereof. The signal generated by the subthreshold stimulus generator **520** may also be modulated in response to the sensed subthreshold pacing signal.

When the control unit **570** determines that the state of the heart is entering in a pre-fibrillation stage, the control unit **570** generates a signal to activate the pre-fibrillation control generator **550**. Pre-fibrillation control generator **550** generates a signal that prevents the onslaught of fibrillation. The stimulus can be managed in amplitude, frequency, and timing (modulation) to be effective. Moreover, the stimulus may be either positive (in that it enhances the natural signal being generated by the heart) or negative (in that is blocks, dampens, or diminishes the natural signal being generated by the heart). The stimulus brings the sensed conditions back to a normal state (points on the Poincaré map back to unity).

Lastly, when the control unit **570** determines that the state of the heart is in a fibrillation stage, the control unit **570** generates a signal to activate the defibrillation pulse generator **560**. Defibrillation pulse generator **560** generates a high voltage pulse to defibrillate the heart.

The methodology utilized by the present invention is illustrated in Figure 5. As illustrated in Figure 5, step **S1** senses the conditions of the heart. If it is determined at step **S2** that the natural pacing signal of the heart falls below a threshold to trigger the heart to beat, step **S3** causes a signal to be generated that causes a threshold of pacing cells in the heart to be exceeded in response to a subthreshold pacing signal or natural stimulus.

If it is determined at step **S4** that the heart is entering in a pre-fibrillation stage, step **S5** causes a signal to be generated that prevents the onslaught of fibrillation. If it is determined at step **S6** that the heart is entering a fibrillation stage, step **S7** causes a high voltage pulse to be generated to defibrillate the heart.

In each of the embodiments described above, the cardiac assist device of the present invention may be contained within a hermetically sealed enclosure, in order to protect the operational components of the device from the harsh environment of the body, as well as to protect the body from the device. The cardiac assist device of the present invention may have a metal case and a connector block mounted to the metal case that includes receptacles for leads which may be used for electrical stimulation or which may be used for sensing of physiological signals. The battery and the circuitry associated with the common implantable pacemaker are hermetically sealed within the case. Electrical interfaces are employed to connect the leads outside the metal case with the medical device circuitry and the battery inside the metal case.

Electrical interfaces serve the purpose of providing an electrical circuit path extending from the interior of a hermetically sealed metal case to an external point outside the case while maintaining the hermetic seal of the case. A conductive path is provided through the interface by a conductive pin that is electrically insulated from the case itself.

Such interfaces typically include a ferrule that permits attachment of the interface to the case, the conductive pin, and a hermetic glass or ceramic seal that supports the pin within the ferrule and isolates the pin from the metal case.

Furthermore, in each of the embodiments described above, the cardiac assist device of the present invention may be constructed to as to be immune or hardened to electromagnetic insult or interference. Although the leads may be fiber optic strands or electrical leads with proper shielding, the actual interface to the tissue, the electrodes, cannot be shielded because the tissue needs to receive the stimulation from the device without interference. This causes the electrodes to be susceptible to electromagnetic interference or insult, and such insult can cause either damage to the tissue area or the circuitry at the other end. To realize immunity from the electromagnetic interference or insult, each electrode has an anti-antenna geometrical shape. The anti-antenna geometrical shape prevents the electrode from picking up and conducting stray electromagnetic interference.

While various examples and embodiments of the present invention have been shown and described, it will be appreciated by those skilled in the art that the spirit and scope of the present invention are not limited to the specific description and drawings herein, but extend to various modifications and changes all as set forth in the following claims.